

Remarks

Claims 1-11 are pending in the subject application. By this Amendment, the applicants have amended claims 1 and 7. Support for the claim amendments can be found in the specification as originally filed. Specifically, support for the recitation of “has activity of inhibiting the proliferation of Gram-positive bacteria” can be found at, for example, page 7, lines 31-32. Support for the recitation of “comprises” can be found at page 16, line 12. No new matter has been added by these amendments. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1-11 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

The amendments set forth herein have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. These amendments should not be taken to indicate the applicants' agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Initially, the applicants have attached herewith replacement drawings to correct a typographical error in Figure 4. Specifically, the phrase “pH4.8ml” has been amended as “pH4.8.”

Claims 1-6 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The applicants respectfully submit that the metes and bounds of the claims, as amended herein, are clear. Accordingly, in view of the claim amendments, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

Claims 1-6 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Izvekova *et al.* The applicants respectfully traverse this rejection.

The current invention provides an antibacterial composition that inhibits the proliferation of Gram-positive bacteria. The composition comprises a fermented dairy product and carbohydrates, proteins and fats. The composition has a pH of 4.6 or less, and the energy ratio of carbohydrates, proteins, and fats contained therein is 50% to 70%, 4% to 25%, and 20% to 30%, respectively.

The Izvekova *et al.* reference does not teach or suggest the currently-claimed composition that inhibits the proliferation of Gram-positive bacteria. As is evidenced by the experimental data

provided in the Expert Declaration of Dr. Hisae Kume filed November 1, 2010 and the Second Expert Declaration of Dr. Hisae Kume attached herewith, one would not expect the Izvekova *et al.* to have any significant antibacterial activity against Gram-positive bacteria. Specifically:

- i) The energy ratio is critical to the antibacterial effect against Gram-positive bacteria, and compositions that do not have the currently-claimed energy ratio have little or no antibacterial activity against Gram-positive bacteria; and
- ii) Compositions prepared from milk have little or no antibacterial effect against Gram-positive bacteria.

Each of these factors is discussed in more detail below.

- i) Energy ratio is critical to the antibacterial effect against Gram-positive bacteria.

As explained in the Second Expert Declaration of Dr. Hisae Kume, the LA lactic acid bacteria beverages, which do not have the claimed energy ratio of carbohydrates, proteins, and fats, have little antibacterial effect against Gram-positive bacteria (see Figure 1 and Table 1 of the Second Expert Declaration of Dr. Hisae Kume). This indicates that the antibacterial effect against Gram-positive bacteria results from the combined effect of the fermented dairy product, the claimed pH value of 4.6 or less and the claimed energy ratio of carbohydrates, proteins, and fats. Compositions that do not have the currently-claimed energy ratio have little or no antibacterial effect against Gram-positive bacteria.

As shown in Appendix A, the energy ratios of the fermented milk products disclosed in Izvekova *et al.* are outside the scope of claim 1. Thus, the fermented milk products of the Izvekova *et al.* reference would not be expected to have a significant antibacterial effect against Gram-positive bacteria.

- ii) Compositions prepared from milk have little or no antibacterial effect against Gram-positive bacteria.

The Izvekova *et al.* reference is directed to compositions prepared from milk, *i.e.*, fermented milk products (see, Title, column 4, lines 16-18 and Examples). As shown in the data provided in Dr. Hisae Kume's Expert Declarations, compositions prepared from milk have little antibacterial effect against Gram-positive bacteria. As shown in Figure 1 of the Expert Declaration of Dr. Hisae Kume filed November 1, 2010, Yogurt 1 and Yogurt 2 have little antibacterial activity

against Gram-positive bacteria MRSA (Yogurt is prepared from milk (see Jing)). Figure 1 of the Second Expert Declaration of Dr. Hisae Kume attached herewith also shows that the Bulgaria Yogurt (Composition (6)) has little antibacterial effect against Gram-positive bacteria. Thus, the fermented milk products disclosed in Izvekova *et al.* would not be expected to have significant antibacterial effect against Gram-positive bacteria.

Consistent with what would be expected by the skilled artisan, the Izvekova *et al.* reference does not teach or suggest any antibacterial effect against Gram-positive bacteria.

Furthermore, evidence that the claimed invention is unexpectedly superior in one of a spectrum of common properties over the prior art can be enough to establish non-obviousness. See *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1988), *In re Sebek*, 465 F.2d 904, 907 (C.C.P.A. 1972), *In re Chupp*, 816 F.2d 643, 646 (Fed. Cir. 1987). The fact that the elements work together in an unexpected and fruitful manner supports the conclusion that the applicants' invention was not obvious to those skilled in the art. *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007), *U.S. v. Adams*, 383 U.S. 39 (1966).

The currently-claimed composition has unexpectedly superior antibacterial activity against Gram-positive bacteria, when compared to the fermented milk compositions disclosed in Izvekova *et al.* As shown in Figure 1, the acidic liquid diet of the current invention has unexpectedly superior antibacterial effects against MRSA, as the viable bacteria counts contained in the 24-hour culture of the currently-claimed composition was 10 cfu/g or less, showing that the bacterial count was lower than the detection limit. In contrast, the viable bacteria counts contained in the 24-hour culture of the lactic acid bacteria beverages of the prior art compositions were determined to be between 10^5 cfu/g and 10^6 cfu/g. This indicates that the unexpectedly superior anti-MRSA activity of the current invention is achieved as a result of the combined effect of the fermented dairy product, the pH value of 4.6 or less and the claimed energy ratio of carbohydrates, proteins and fats.

In conclusion, the Izvekova *et al.* reference does not teach or suggest the currently-claimed composition that has antibacterial effects against Gram-positive bacteria. Furthermore, the unexpectedly superior antibacterial activity against MRSA evidences that the applicants' invention

is not obvious. Accordingly, the applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a).

Claims 1-5 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Jing (China Health Monthly 8:102-103, 2003). The applicants respectfully traverse this rejection.

The Jing reference does not teach or suggest the current invention. Specifically, the Jing *et al.* reference is directed to yogurt products – fermented milk preparations. It does not teach or suggest the current invention that comprises, in addition to a fermented dairy product, other carbohydrates, proteins, and fats.

The Jing reference also does not teach or suggest the current composition that has the energy ratio of carbohydrates, proteins, and fats of 50% to 70%, 4% to 25%, and 20% to 30%, respectively. Instead, as shown in Table A below, the energy ratio of the yogurt disclosed in the Jing reference is outside of the scope of claim 1.

Table A. Comparison of the Energy Ratio of Carbohydrates, Proteins, and Fats of the Jing's Yogurt Composition and the Current Invention

	Weight Percent of Jing's Yogurt	Energy Ratio of Jing's Yogurt	The Energy Ratio of Claim 1
Proteins	2.5g	13.89%	4% to 25%
Fats	2.7g	33.75%	20% to 30%
Carbohydrates	9.3g	51%	50% to 70%

In addition, the Jing reference does not teach or suggest any composition that inhibits the proliferation of Gram-positive bacteria. The bacteria mentioned in the Jing reference are *E. coli* – Gram-negative bacteria. As shown in the second Expert Declaration of Dr. Hisae Kume, fermented milk compositions that do not have the claimed energy ratio of carbohydrates, proteins, and fats do not have antibacterial effects against Gram-positive bacteria. Also, yogurts have little or no antibacterial effects against Gram-positive bacteria (*see* Figure 1 of the Expert Declaration of Dr. Hisae Kume filed November 1, 2010 with regard to Yogurt 1 and Yogurt 2; Figure 1 of the

Second Expert Declaration of Dr. Hisae Kume attached herewith with regard to Bulgaria Yogurt (Composition (6)). Thus, the yogurt compositions disclosed by the Jing reference have little or no antibacterial effects against Gram-positive bacteria.

As noted above, evidence that the claimed invention is unexpectedly superior in one of a spectrum of common properties over the prior art can be enough to establish non-obviousness. See *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1988), *In re Sebek*, 465 F.2d 904, 907 (C.C.P.A. 1972), *In re Chupp*, 816 F.2d 643, 646 (Fed. Cir. 1987). The fact that the elements work together in an unexpected and fruitful manner supports the conclusion that the applicants' invention was not obvious to those skilled in the art. *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007), *U.S. v. Adams*, 383 U.S. 39 (1966).

The currently-claimed composition has unexpectedly superior antibacterial activity against Gram-positive bacteria, when compared to the yogurt compositions disclosed in the Jing reference. Specifically, the viable bacteria counts contained in the 24-hour culture of the currently-claimed composition was 10 cfu/g or less, showing that the bacterial count was lower than the detection limit. In contrast, the viable bacteria counts contained in the 24-hour culture of the yogurt compositions were determined to be between 10^5 cfu/g and 10^6 cfu/g (see Figure 1 of the Expert Declaration of Dr. Hisae Kume filed November 1, 2010 with regard to Yogurt 1 and Yogurt 2; Figure 1 of the Second Expert Declaration of Dr. Hisae Kume attached herewith with regard to Bulgaria Yogurt (Composition (6)). This indicates that the unexpectedly superior anti-MRSA activity of the current invention is achieved by the combined effect of the fermented dairy product, the pH value of 4.6 or less and the claimed energy ratio of carbohydrates, proteins and fats.

In conclusion, the Jing reference does not teach or suggest the currently-claimed composition that has antibacterial effects against Gram-positive bacteria. Furthermore, the unexpectedly superior antibacterial activity against MRSA evidences that the applicants' invention is not obvious. Accordingly, the applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a).

Claim 6 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Jing as applied to claims 1-5 above, and further in view of Izvekova *et al*. The applicants respectfully traverse this rejection.

The deficiencies of Jing and Izvekova *et al.* are discussed above. The references, taken either alone or in combination, do not teach or suggest any composition that has antibacterial effect against Gram-positive bacteria. Further, the unexpectedly superior antibacterial effect against MRSA evidences that the applicants' invention is not obvious. Accordingly, the applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a).

Claims 7-11 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Jing as applied to claims 1-5 above, and further in view of Egli (U.S. Patent No. 3,932,680). The applicants respectfully traverse this rejection.

As discussed above, Jing does not teach or suggest the currently-claimed method, wherein the fermented dairy product is mixed with additional carbohydrates, proteins, and fats, and the mixture is homogenized and sterilized. In addition, the Jing reference does not teach or suggest the preparation of a composition that inhibits the proliferation of Gram-positive bacteria.

The Egli reference does not cure the deficiencies of the Jing reference. Instead, as noted in the Office Action at page 4, Egli teaches homogenizing yogurt and sterilizing the homogenized yogurt. Egli also does not teach or suggest the currently-claimed method for preparing a composition having antibacterial effects against Gram-positive bacteria. As discussed above, yogurt products have little or no antibacterial effect against Gram-positive bacteria.

With regard to claims 9 and 10, the cited references also do not teach or suggest that proteins of the fermented dairy product account for 30 weight % or more of the proteins in the composition (claim 9) or proteins of the fermented dairy product account for 70 weight % or more of the proteins in the composition (claim 10).

Thus, the references, even when combined, do not teach or suggest claims 7-11. Accordingly, the applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a).

In view of the foregoing remarks and the amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



David R. Saliwanchik
Patent Attorney
Registration No. 31,794
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: P.O. Box 142950
Gainesville, FL 32614-2950

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Attachments: Second Declaration of Dr. Hisae Kume under C.F.R. 1.132
Appendix A
Replacement drawing